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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,788	03/26/2004	Diane M. Ruezinsky	MONS:060US	9881

46795 7590 07/03/2006

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EXAMINER

PAGE, BRENT T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/810,788	<b>Applicant(s)</b> RUEZINSKY, DIANE M.	
	<b>Examiner</b> Brent Page	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Arguments***

The cancellation of claim 11 without prejudice by Applicant is acknowledged.

Applicant's arguments, filed 04/13/2006, with respect to the definition of the term "fragment" have been fully considered and are persuasive. The rejection of claims 1-10 and 12-13 under 35 U.S.C. 112, second paragraph-Indefiniteness, has been withdrawn.

Applicant's arguments, filed 04/13/2006, with respect to the anticipation of SEQ ID NO:4 by Johnson-Hopson have been fully considered and are persuasive when taken together with the amendment of the claims wherein they are drawn to an "isolated" polynucleotide sequence and "wherein the promoter is operably linked to a transcribable polynucleotide molecule". The rejection of claim 1 under 35 U.S.C. 102(b) based on anticipation by Johnson-Hopson has been withdrawn.

Applicant's amendment of claims 1 and 10 in the Claims filed on 04/13/2006 have resulted in the withdrawal of the rejection of claims 1 and 10 under 35 U.S.C. 101.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-10 and 12-13 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as stated on pages 3-5 of the previous office action.

Applicant's arguments filed 13 April 2006 have been fully considered but they are not persuasive. Applicant argues that the Kim et al reference does not apply to the current application because the promoter discussed is the *nos* promoter from the bacteria *Agrobacterium tumefaciens*, whereas the sequence of SEQ ID NO:4 is isolated from *Arabidopsis thaliana*. Applicant urges that the enablement rejection is improper, given the newly submitted art that describe altered and modified promoter sequences. Applicant further urges that such alterations and modifications are routine experimentation in the art.

The Examiner maintains that the unpredictability of promoter function demonstrated by Kim et al is relevant to the instant application as broadly claimed. The instant application does not specify that the claimed promoter must be of plant origin, only that it comprises a fragment of SEQ ID NO:4 or a sequence with at least 70% identity to a fragment of SEQ ID NO:4. The Examiner maintains that a "fragment" of SEQ ID NO:4 is directed to a sequence that contains as little as one base from SEQ ID NO:4, which reads on promoters from any organism. The specification does not give guidance on how to make and use such promoters in transgenic plants, and the Examiner maintains that

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function in plants would be unpredictable and that evaluation of such a wide range of promoters would be undue experimentation, and not, routine in the art. The experimentation described in the specification is not sufficient for evaluation of every sequence variant claimed by Applicant. Furthermore, examples of "functioning" promoters given by Applicant that are routinely modified or altered promoters have either reduced or increased activity as in the case of the psy promoter from exhibit A that showed a 20-30% decrease in activity of a truncated version of the promoter. There is no guidance in the specification, particularly in regard to claims 7-9, that would enable one of skill in the art to make and use such promoters with reduced activity in conferring altered oil, micronutrient, or protein content in a transgenic plant.

See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Claims 1-10 and 12-13 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention as stated on pages 5-8 of the previous office action.

Applicant's arguments filed 13 April 2006 have been fully considered but they are not persuasive. Applicant urges that the written description rejection is

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improper given that all fragments of SEQ ID NO:4 have literal written support in the sequence listing and given that the specification describes the creation of variants of SEQ ID NO:4.

The Examiner maintains that the claims broadly encompass promoters comprising any fragment of SEQ ID NO:4 including as little as a single base pair. There is an infinite number of sequences that would comprise a fragment of SEQ ID NO:4, and as such there is not support in the specification to make and use all sequences comprising a fragment of SEQ ID NO:4 as broadly claimed. There are also a multitude of sequence variants of SEQ ID NO:4 that are encompassed by the claim. There is not support in the specification to make and use all such sequence variants.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 12 remain rejected under 35 U.S.C. 102(b) as being anticipated by McElroy et al (US Patent 6207879) as stated on pages 9-10 of the previous office action.

Applicant's arguments filed 13 April 2006 have been fully considered but they are not persuasive. Applicant urges that the prior art rejection is improper based on a BLAST alignment between the RS81 promoter and SEQ ID NO:4

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showing no significant similarity and also that a single base pair would not comprise promoter activity.

The Examiner maintains that the Applicants broadly claimed a promoter **comprising** a fragment of SEQ ID NO:4 or a promoter exhibiting a percentage identity of between about 70% identity and 79% identity with a polynucleotide sequence **comprising** a fragment of SEQ ID NO:4. Therefore, a BLAST alignment with entire SEQ ID NO:4 only represents **one** embodiment of the claimed invention, and it is inherent that other embodiments in fact, would read upon the claimed invention, including an embodiment that is the RS81 promoter.

Claims 1-3, 5-7, 10 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Debonte et al (US Patent 5850026) as stated on pages 10-11 of the previous office action.

Applicant's arguments filed 13 April 2006 have been fully considered but they are not persuasive. Applicant urges that the prior art rejection is improper based on a single base pair not having promoter function and also that DeBonte et al do not disclose any promoter sequences.

The Examiner maintains that the Applicants broadly claimed a promoter **comprising** a fragment of SEQ ID NO:4 or a promoter exhibiting a percentage identity of between about 70% identity and 79% identity with a polynucleotide sequence **comprising** a fragment of SEQ ID NO:4. The Examiner interprets "fragment" to be as little as a single base pair as the specification does not provide a definition that would dispute this. DeBonte et al disclose a number of promoters including numerous phaseolin promoter fragments which would

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inherently comprise at least a single base pair of SEQ ID NO:4 (see Column 10 the last two paragraphs, for example).

No Claim is free of the prior art.

No Claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (514)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

